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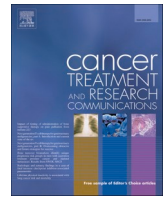
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Learning curve in robotic-assisted lobectomy for non-small cell lung cancer is not steep after experience in video-assisted lobectomy; single-surgeon experience using cumulative sum analysis

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ABSTRACT

Background: Robotic assistance in lung lobectomy has been suggested to enhance the adoption of minimally invasive techniques among surgeons. However, little is known of learning curves in different minimally invasive techniques. We studied learning curves in robotic-assisted versus video-assisted lobectomies for lung cancer.

Methods: A single surgeon performed his first 75 video-assisted thoracic surgery (VATS) lobectomies from April 2007 to November 2012, and his 75 first robotic-assisted thoracic surgery (RATS) lobectomies between August 2011 and May 2018. A retrospective chart review was done. Cumulative sum (CUSUM) analysis was used to identify the learning curve.

Results: No operative deaths occurred for VATS patients or RATS patients. Conversion-to-open rate was significantly lower in the RATS group (2.7% vs. 13.3%, $p = 0.016$). Meanwhile, 90-day mortality (1.3% vs. 5.3%, $p = 0.172$), postoperative complications (24% vs. 24%, $p = 0.999$), re-operation rates (4% vs. 5.3%, $p = 0.688$), operation time (170 ± 56 min vs. 178 ± 66 min, $p = 0.663$) and length of stay (8.9 ± 7.9 days vs. 8.2 ± 5.8 days, $p = 0.844$) were similar between the two groups. Based on CUSUM analysis, learning curves were similar for both procedures, although slightly shorter for RATS (proficiency obtained with 53 VATS cases vs. 45 RATS cases, $p = 0.198$).

Conclusions: Robotic-assisted thoracoscopic lung lobectomy can be implemented safely and efficiently in an expert center with earlier experience in VATS lobectomies. However, there seems to be a learning curve of its own despite the surgeon's previous experience in conventional thoracoscopic surgery.

Introduction

Anatomic VATS lung resections are associated with decreased morbidity relative to the conventional open approach in non-small cell lung cancer (NSCLC), especially for early-stage disease [1-3]. Still adoption of anatomic VATS pulmonary resections has been slow and has been considered by many to be due to a demanding learning curve with the possibility of life-threatening vascular complications [4].

The first anatomic robotic-assisted thoracic surgery (RATS) for NSCLC was reported in 2002 [5]. In recent years, several studies have been published in the field, demonstrating that RATS lobectomy is also a safe and feasible approach for the treatment of NSCLC [6, 7, 8, 9]. In 2012, a total of 10 161 lung resections were reported for NSCLC in the

United States to The Surveillance, Epidemiology, and End Results (SEER) database. Of these, 2934 (29%) were performed with VATS, and 1055 (10.4%) were robotically assisted. RATS has demonstrated superiority over VATS with shorter hospital stay and reduced postoperative pain [7,9-11]. Recently, Liang et al. [12] published a meta-analysis where the 30-day mortality and conversion to open rate was significantly lower in RATS than in VATS [12]. Compared with VATS, the advantages of RATS include broader and more agile movement of instruments, three-dimensional visualization of the operative area, minimal hand tremor, and improved surgeon ergonomics [13,14]. These advantages have raised expectations for shorter learning curves for robotic-assisted lung lobectomies.

When implementing a new surgical technique, the learning curve

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should also be evaluated for patient safety and resident training. The learning curve involves a number of key factors that include the surgeon's previous experience, particularly with similar procedures. Our initial goal was to analyze the surgical outcomes and learning curve for one surgeon in his first 75 VATS and his first 75 RATS for the treatment of NSCLC. We have applied cumulative sum (CUSUM) analysis on initial VATS and RATS lobectomies to find a target case number for gaining technical proficiency.

Patients and methods

One surgeon (J.R.) operated on his first 75 VATS patients between April 2007 and November 2012, and the same surgeon operated on his first 75 RATS patients between August 2012 and May 2018 in the Division of General Thoracic and Esophageal Surgery of Helsinki University Central Hospital. The study was a retrospective cohort study between VATS and RATS anatomic lobectomies. All patients were discussed at a multidisciplinary Diagnostic Management Team (DMT) meeting before the operation. All operations were analyzed on an intention-to-treat basis, which takes conversions to conventional open surgery into account.

All patients completed preoperative computed tomography (CT) and pulmonary function tests (PFTs): data from spirometry studies (FEV1, FVC, and FEV1/FVC), and pulmonary diffusion capacity measurements (DLco) were recorded from patients' medical records. The additional need for positron emission computed tomography (PET-CT), bronchoscopy, mediastinoscopy, CT-guided core needle biopsy, the stair-climbing test, ventilation-perfusion scanning, and maximal oxygen uptake (VO₂max) testing was decided on an individual basis. For staging, the 8th edition of the TNM classification was utilized collectively [15]. The status of comorbidity was objectively quantified based on the Charlson Comorbidity Index (CCI) [16]. Postoperative hospital stay (from the day of the surgical procedure to the day of discharge), conversion (defined as unplanned extension of the incision and rib spreading beyond that required for specimen extraction), postoperative complications (defined as Grade 3 or above for severe complications under the Clavien-Dindo classification system within 30 postoperative days) [17], and 90-day mortality (defined as death during the same hospitalization or within 90 days after the operation). Consent was granted for the study by the Hospital Ethics Review Board.

Operative techniques

All procedures were performed in the lateral decubitus position with hilar dissection and individual ligation of hilar structures. VATS

lobectomy was performed using the anterior approach described by Hansen et al. [18] with three incisions (Fig. 1). Rib spreading was not used in any VATS procedure. No routine CO₂ insufflation was used.

RATS lobectomies were carried out with a 4-armed approach (three 8-mm ports and a 12-mm camera port). The 12-mm utility port and 8 mmHg CO₂ insufflation were used (DaVinci Si, Intuitive Surgical, Sunnyvale, CA, USA) (Fig. 2). All hilar structures were individually dissected and ligated using automatic stapling devices. Fissures were completed with either sharp dissection or an automatic stapling device, depending on the completeness of the fissures. The anterior costophrenic utility port was enlarged near the end of the procedure to allow for specimen retrieval in a plastic endobag. Local anesthetic (ropivacaine) was used similarly in both operations.

All patients underwent systematic lymph node sampling or lymph node dissection. Reported operative time was skin-to-skin. Characteristics of the study patients and their clinical data were collected from patient records. Preoperative data are presented in Table 1.

Statistical analysis

Statistical analysis was performed using SPSS statistical software (version 25.0, Chicago, IL, USA). Results are reported as median (range) or mean \pm standard deviation. The Student's *t*-test was used to compare parametric values of groups, while the Mann-Whitney *U* test was performed to compare nonparametric data between groups. Comparisons of survival were carried out using the log-rank test. A *p*-value of less than 0.05 was considered statistically significant.

Cumulative sum analysis

A CUSUM analysis was performed for the duration of the operation. The patients were categorized in chronological order. The results were presented in CUSUM charts, which are a graphical presentation of the course of outcomes of a series of consecutive procedures performed over time. The CUSUM curve runs randomly at or above a horizontal line at an acceptable level of performance (no slope). However, the CUSUM curve slopes upward and will eventually cross a decision interval when an operation is performed at an unacceptable level. These are horizontal lines drawn across the CUSUM chart. The degree of the slope is a measure of a surgeon's progress in mastering a new skill: the higher the slope, the slower the progress. The surgeon has mastered the new skill when the curve eventually flattens (no slope) [19]. According to the CUSUM analysis conducted for the duration of the operations, the cut-off point was when the curve flattened, suggesting that the operative time was almost equal to the average operative time.

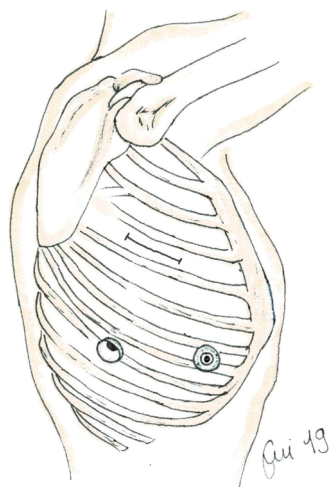


Fig. 1. Operative image of the setup of VATS surgery.

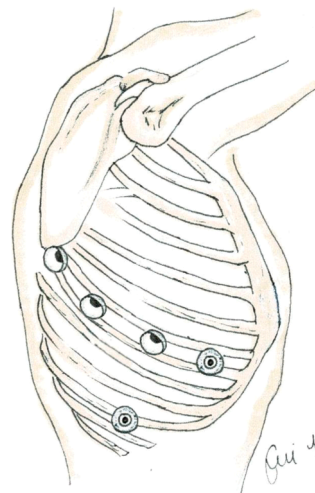


Fig. 2. operative image of the setup of RATS.

Table 1
Patient baseline characteristics and perioperative outcomes.

All patients n = 150	VATS (n = 75)	RATS (n = 75)	P*	Early- experience VATS (n = 53)	Early- experience RATS (n = 45)	P*	Late- experience VATS (n = 22)	Late- experience RATS (n = 30)	P*
Age (mean ± SD)	66.9 (±9.1)	70.6 (±7.6)	0.405	67.3(±7.8)	69.7 (±7.5)	0.119	68.66 (±7.5)	67.1 (±9.2)	0.523
Female, n (%)	32 (42.7%)	38 (50.7%)	0.416	22 (43.1%)	22 (51.2%)	0.801	12 (50%)	17 (53.1%)	0.818
Smokers, n (%)	65 (86.7%)	63 (84%)	0.815	44 (86.3%)	37 (82.2%)	0.974	21 (87.5%)	27 (90%)	0.743
FEV1 ₁ (mean±SD)	69.5 (±15.7)	78.5 (±17.3)	0.001	71.3 (±11.6)	73.1 (±13.3)	0.889	63.6 (±15.3)	85.3 (±18.2)	0.000
DLco (mean ± SD)	71.2 (±17.8)	77.6 (±22.9)	0.526	72.2 (±17.3)	74.5 (±19.6)	0.604	73.4 (±17.8)	79.7 (±20.1)	0.302
CCI (mean± SD)	3.1 (±0.9)	2.9 (±1.4)	0.372	3.1 (±0.7)	3.28 (±0.6)	0.207	3.1 (±0.8)	2.5 (±0.9)	0.015
Preoperative Stage, n (%)			0.582			0.736			0.255
IA	48 (64%)	52 (69.3%)		35 (66%)	29 (64.4%)		14 (64.4%)	23 (76.7%)	
IB	14 (18.7%)	13 (17.3%)		11 (20.8%)	8 (17.8%)		3 (13.6%)	5 (16.7%)	
IIA	6 (8%)	4 (5.3%)		3 (5.7%)	3 (6.7%)		2 (9.1%)	1 (3.3%)	
IIB	4 (5.3%)	4 (5.3%)		3 (5.7%)	4 (8.9%)		1 (4.5%)	0	
IIIA	3 (4%)	2 (2.7%)		1 (1.9%)	1 (2.2%)		2 (9.1%)	1 (3.3%)	
Resected lobe, n (%)			0.470			0.813			0.564
RUL	27 (36%)	25 (33.3%)		18 (34%)	18 (40%)		8 (36.4%)	7 (23.3%)	
RML	3 (4%)	5 (6.7%)		2 (3.8%)	2 (4.4%)		1 (4.5%)	3 (10%)	
RLL	18 (24%)	13 (17.3%)		15 (28.3%)	9 (20%)		3 (13.6%)	5 (16.7%)	
LUL	19 (25.3%)	14(18.7%)		14 (26.4%)	7 (15.6%)		6 (27.3%)	6 (20%)	
LLL	5 (6.7%)	15 (20%)		2 (3.8%)	7 (15.6%)		3 (13.6%)	8 (26.7%)	
BiL	3 (4%)	3 (4%)		2 (3.8%)	2 (4.4%)		1 (4.2%)	1 (3.3%)	
OR Time, minutes (mean±SD)	170±56	178±66	0.663	183±51	196±71	0.284	143±32	155±39	0.246
Resected lobe, mean OPT (n)									
Upper lobes	173 (46)	178 (38)	0.723	184 (32)	189 (25)	0.709	152 (14)	159 (13)	0.711
Lower lobes	169 (23)	178 (29)	0.949	185 (17)	201 (16)	0.594	131 (6)	152 (13)	0.126
other	148 (6)	184 (8)		160 (4)	221 (4)		125 (2)	147 (4)	
Conversion to open rate, n (%)	10 (13.3%)	2(2.7%)	0.016	10 (19.6%)	1 (2.2%)	0.010	0	1 (3.3%)	0.386
Complications (grade >2), n (%)	22 (29.3%)	21 (28%)	0.044	11 (21.6%)	11 (24.4%)	0.426	8 (33.3%)	9 (30%)	0.072
Arrythmia	4 (5.3%)	3 (4%)		1 (1.9%)	0		3 (13.6%)	3 (10%)	
Prologed air leak	9 (12%)	3 (4%)		5 (9.4%)	3 (6.7%)		4 (18.2%)	0	
Pneumonia	5 (6.7%)	9 (12%)		4 (7.5%)	6 (13.3%)		1 (4.5%)	3 (10%)	
Empyema	1 (1.3%)	2 (2.7%)		1 (1.9%)	1 (2.2%)		0	1 (3.3%)	
ARDS	1(1.3%)	2 (2.7%)		0	1 (2.2%)		0	2 (6.7%)	
Re-operations, n (%)	3 (4%)	4 (5.3%)	0.688	1 (1.9%)	2 (4.4%)	0.438	2 (9.1%)	2 (6.7%)	0.733
Hospital days, (mean±SD)	8.9 ± 7.9	8.2 ± 5.8	0.844	8.4 ± 7.6	8.4 ± 6.2	0.991	7.6 ± 5.6	7.9 ± 5.3	0.611
Discharge status			0.788			0.804			0.865
Home	69 (92%)	67 (89.3%)		47 (88.7%)	40 (88.9%)		20 (90.9%)	27 (90%)	
Health center	6 (8%)	8 (10.7%)		4 (7.5%)	5 (11.1%)		2 (9.1%)	3 (10%)	
Mortality 30d, n (%)	0 (0%)	4 (5.3%)	0.043	0	1 (2.2%)	0.287	0	3 (10%)	0.114

VATS, video-assisted thoracoscopic surgery; RATS, robotic-assisted thoracoscopic surgery; SD, Standard deviation; CCI, Charlson comorbidity index; FEV₁ Forced expiratory volume in one second; DLco, pulmonary diffusing capacity for carbon monoxide. RUL=Right upper lobe; RML=Right median lobe; RLL=Right lower lobe; LUL=Left upper lobe; LLL=Left lower lobe; BiL=Bilobectomy (Right median and right upper/lower lobe), OR, Operation time; SD, Standard deviation; 30d, thirty days mortality; *X² for categorical variables and 2-sample rank sum test for continuous variables.

Results

Seventy-five patients underwent VATS lobectomies between April 2007 and November 2012, and another 75 patients underwent RATS lobectomies between August 2012 and May 2018 (Table 1.) No differences were noted between RATS and VATS patients in age, sex, smoking status, CCI, or clinical disease stage. The VATS group had inferior preoperative FEV₁ (p = 0.001). The mean operative time was 170±56 min for VATS and 178±66 min for RATS (p = 0.663). There was a significantly lower conversion to open rate in the RATS group (2.7% vs. 13.3%, p = 0.016). Both conversions for RATS were because of intraoperative bleeding. In the VATS group, all conversions were among the first 53 cases, three of them because of intraoperative bleeding and seven because of difficulties in recognizing the anatomy. There were no

operative deaths for VATS patients or RATS patients. No difference was noted in re-operation rates or postoperative complications (Grade 3 or above based on Clavien-Dindo classification) (4% vs. 5.3%, p = 0.688 and 24% vs. 24%, p = 0.099). There was a trend toward more air leaks in the VATS group (12% vs. 4%, p = 0.071). Length of stay was similar between the groups (8.9 ± 7.9 days vs. 8.2 ± 5.8 days, p = 0.844). Both groups were equally discharged to home (92% for VATS and 89.3% for RATS). The 90-day mortality in the RATS group was 5.3% and in the VATS group 1.3% (p = 0.172).

Learning curve

The learning curve was assessed by the CUSUM method. Cut off point was reached after 53 VATS cases and 45 RATS cases (Figs. 3 and 4). As

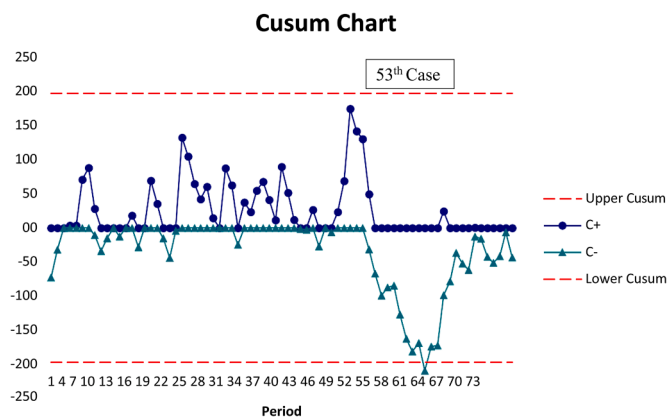


Fig. 3. Cusum chart for 75 VATS operation time. CUSUM, cumulative sum.

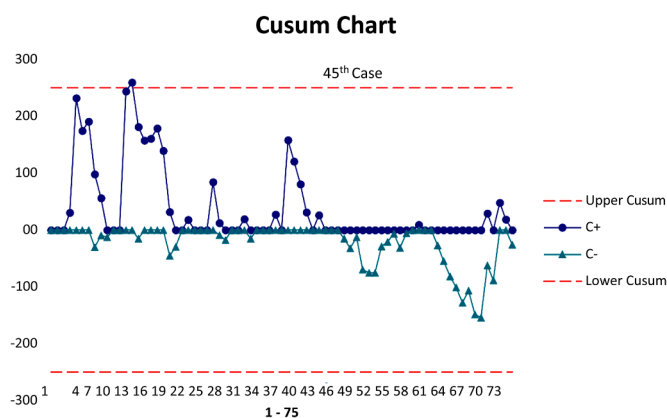


Fig. 4. Cusum chart for 75 RATS operation time. CUSUM, cumulative sum.

these results indicated that the learning curve for VATS for lung cancer peaked at 53 cases and for RATS at 45 cases, we divided both sets of patients into two groups: early VATS experience group ($n = 53$), early RATS experience group ($n = 45$), late VATS experience group ($n = 22$), and late RATS experience group ($n = 30$) (Table 1).

Demographic and clinical characteristics of the four groups are reported in Table 1. There were no significant differences in patients' age, sex, smoking status, CCI, or clinical disease stage. For the early VATS group, the mean OPT was 183 min, and for the late VATS group 143 min ($p = 0.002$). For the early RATS group, the average OPT was 196 min, and for the late RATS group it decreased to 155 min ($p = 0.001$). When we compared OPT of lower lobes with OPT of upper lobes in both VATS and RATS groups, no significant differences emerged. The learning curves of RATS lower and upper lobectomies were 16 and 14 cases, respectively (Fig. 5A and B). For VATS lower and upper lobectomies, the learning curves were 19 and 27 cases, respectively (Fig. 6A and B).

Comment

In this study, both VATS and RATS were found to be safe and feasible approaches. The learning curves were similar for both procedures, albeit slightly shorter for RATS, with proficiency obtained with 53 cases for VATS and 45 cases for RATS.

Both VATS and RATS offer minimally invasive approaches in patients. Lee et al. [20] compared VATS and RATS lobectomies, finding that both approaches were similar in mortality, morbidity, and length of stay. Cao et al. [21] conducted a systematic review and meta-analysis of pulmonary resections by robotic/video-assisted thoracic surgery, and reported the most common postoperative complications to be tachyarrhythmias (3–19%), prolonged air leak (4–13%), pneumonia (1–5%),

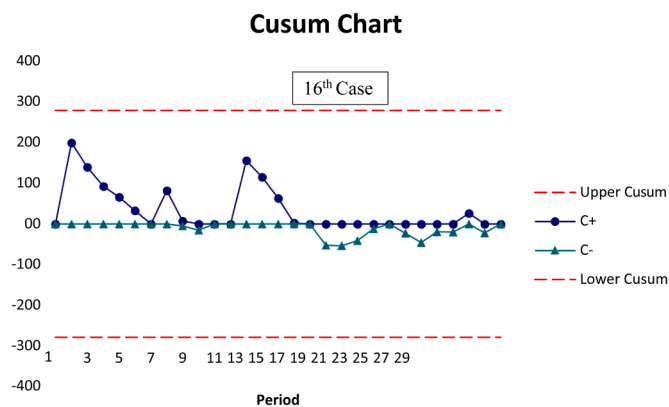


Fig. 5A. Cusum chart for 29 RATS inferior lobes operation time. CUSUM, cumulative sum.

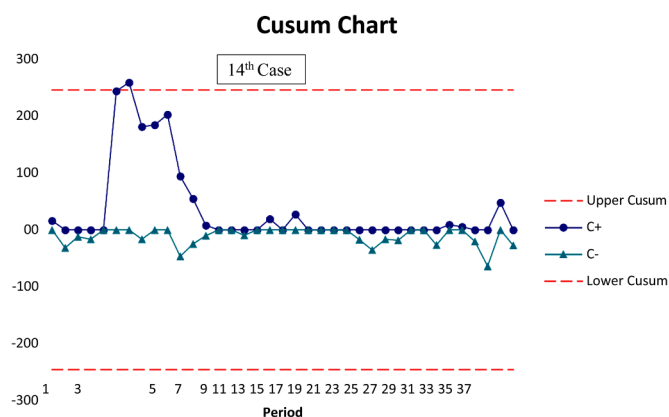


Fig. 5B. Cusum chart for 37 RATS superior lobes operation time. CUSUM, cumulative sum.

and acute respiratory distress (1–4%) [21]. In our series, there was a trend for prolonged air leaks in the VATS group relative to the RATS group (12% vs. 4%, $p = 0.071$), and arrhythmia developed in 5.3% of VATS patients and in 4% of RATS patients, consistent with the literature [21,22].

There are several reports of operative time for RATS ranging between 132 and 226 min [14,23–27] and for VATS between 120 and 180 min [1, 4,28,29]. In our recent study robotic-assisted surgery took on average only 8 min longer than the thoracoscopic operation. This result differs from previous studies, where RATS OPT has been longer than VATS OPT [7,11,30]. This difference can be partly explained that robotic program started after established experience with the VATS program and the surgeons background with other minimally invasive techniques.

A recent study shows significantly lower conversion rates in RATS procedures (4.8%) than in VATS procedures (8.0%) performed by an experienced thoracic surgeon [31]. Cerfolio [35] reported the incidence of major vascular injury during elective robotic lobectomy to be 2.6%. In our study, both conversions in the RATS group were because of iatrogenic bleeding while dissecting the branches of the pulmonary artery. In the VATS group, there were three conversions because of bleeding and seven because of difficulties in identifying anatomy. These conversions were all in the 53 early VATS lobectomies. Mei et al. [32] reported a vascular injury rate of 4.1% in VATS anatomical resections. In a paper by Decaluwe [33] conversion to open thoracotomy was observed in 5.5% of patients: 29.4% for technical reasons, 2.9% for vascular injuries, and

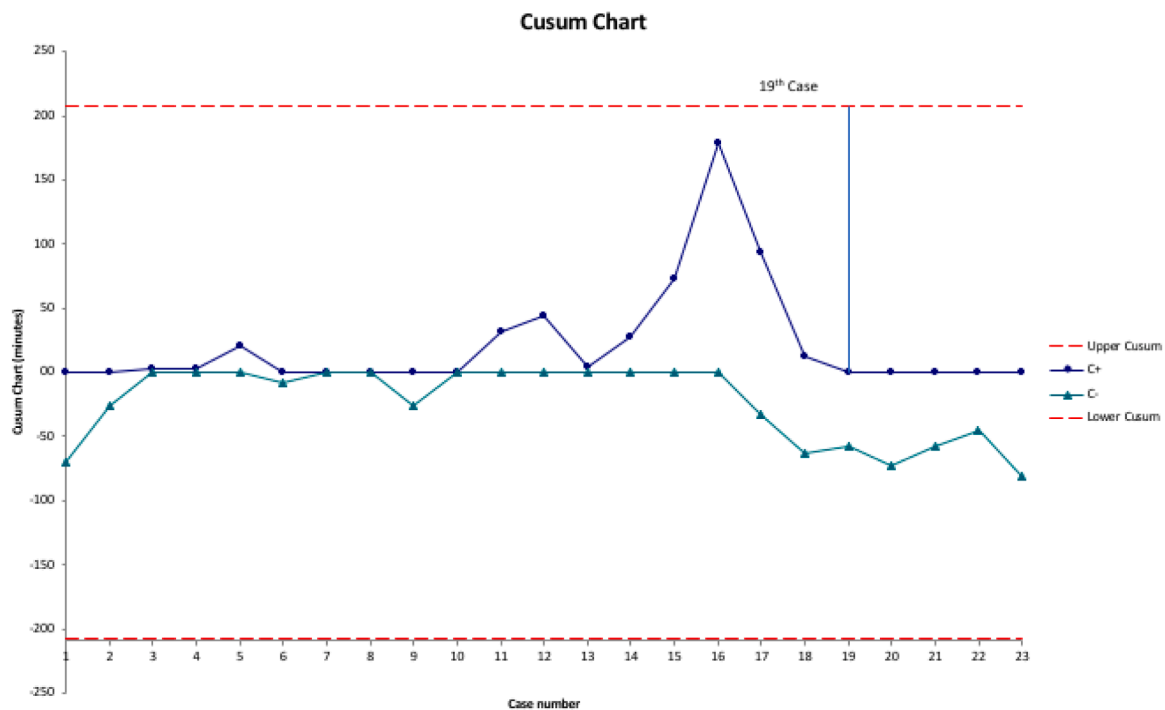


Fig. 6A. Cusum chart for VATS inferior lobes operation time. CUSUM, cumulative sum.

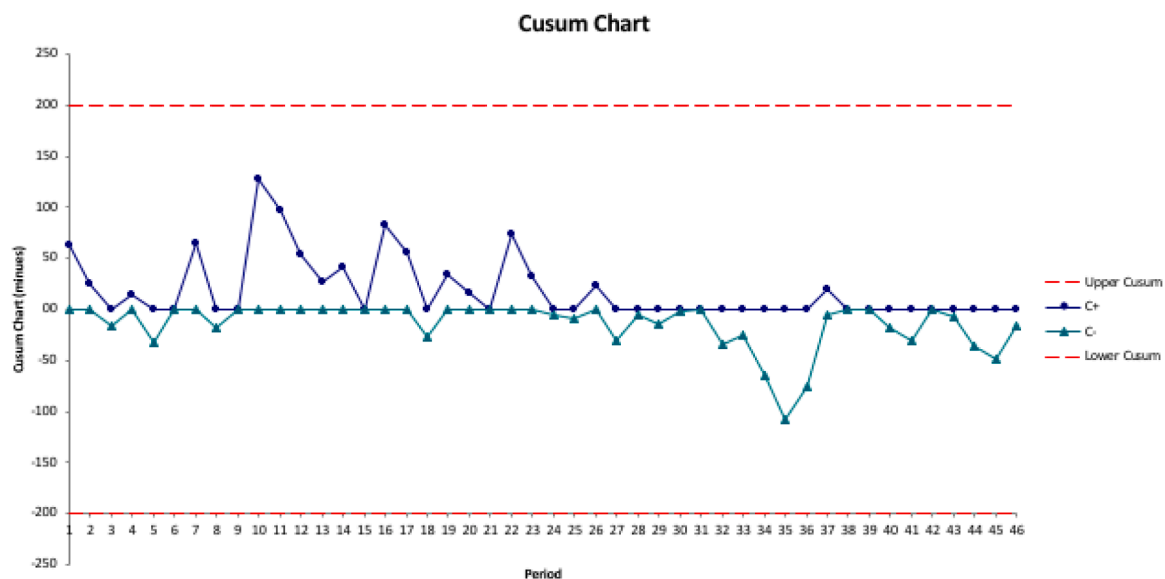


Fig. 6B. Cusum chart for VATS superior lobes operation time. CUSUM, cumulative sum.

41.2% for bleeding. In our center, the main reason for conversions in the VATS group was dense hilar adhesion and distorted anatomy because of the pathological process. Conversions in the early VATS group reflect the surgeon’s learning curve. Also, the threshold for open surgery was lower at the beginning of the learning process. RATS seemed to be favorable when dealing with adhesions and recognizing anatomy because there were no conversions for these reasons in the RATS group. Our paper supports the statement that tears of pulmonary vessels are the main reasons for conversions in both minimally invasive techniques [25,27, 34].

Neither group had intraoperative deaths, nor was there a statistical difference in 90-day mortality. Four patients died in the RATS cohort (two ARDS, one lung fibrosis worsening, and one heart failure), and one

patient in the VATS cohort (cardiac arrest 37 days postoperatively). In numerous studies, VATS and RATS mortality rates are reported to be similar, ranging from 1.3% to 4.3% [2,13,27,31,34]. However, Gharagozloo [23] reported their first 100 RATS cases; 30-day mortality among the first 20 patients was 15%. They concluded that in patients with poor FEV1 and ^{DLco} the lung does not collapse, and robotic and endoscopic VATS maneuvers are inhibited because of the limited pleural space. This will lead to longer operative times and may contribute to postoperative complications and poor outcome [23]. We think that this was also the case with our patients. These deaths were not related to major intraoperative complications, and there was no statistical difference in the 90-day mortality of patients, so it can be concluded that the VATS nor RATS procedure does not jeopardize patients.

The slow adoption of VATS is considered by many to be due to a demanding learning curve [4]. The International VATS Lobectomy Consensus Group suggested that 50 cases are required for technical proficiency in VATS lobectomy [35]. McKenna indicated 50 cases for the point at which surgeons feel comfortable with the procedure [36,37]. The learning curve for VATS surgery can set between 20 and 50 cases. In this study, the learning curve for VATS lobectomies was consistent with earlier studies.

The learning curve for robotic lobectomy has varied in different publications [25,26]. In our paper, the inflection point for decreasing operative time was 45 RATS cases. A recent paper by Arnold et al. [22], showed that based on operating time the learning curve for RATS lobectomy is 22 cases, with mastery achieved after 63 cases [22]. In their research, operation time after 63 lobectomies was 168 min, which is in line with our results. Although robotics offers excellent three-dimensional imaging and dexterity, there are also a few drawbacks. First, the operator lacks the sensation of tissue manipulation, which is the case for both open and VATS surgery. Second, the physical distance to the rest of the team, with the surgeon sitting 5 m away, poses a challenge to the teamwork. The third challenge for the RATS lobectomy learning process is access to the robot and the number of RATS in lobectomy cases. In our department, we initially had robot access only every other week, which may have prolonged the learning curve.

Study strengths and limitations

A strength of our study is that the operations were performed during relatively short periods. The cases were performed by one surgeon, which makes it possible to compare the learning curves of the surgeon. Our study also has a few limitations. It represents the learning curve of a single surgeon with earlier experience in conventional open, VATS and RATS thoracic surgery. One might ask whether these results can be reproduced by a new learner with little or no experience in conventional open surgery. Furthermore, we have a relatively small number of patients, and the study was retrospective in nature. This increases the risk of selection bias.

Conclusion

Although RATS lobectomies can be implemented safely in an expert center with previous experience in VATS lobectomies, a significant learning curve exists even for an experienced VATS surgeon. The learning curves for VATS lobectomies and RATS lobectomies are very similar and almost equal in length, with minor differences in nature. The advantage of using a robot to assist in VATS lobectomies seems to be the easier recognition of anatomical structures, however, the lack of haptic feedback complicates the handling of delicate tissues.

Authors' contributions

Saana Andersson prepared the manuscript and coordinate the study. Ilkka Ilonen helped prepare the manuscript and provided adequate statistical substantiation of the manuscript. Otto Pälli, Jarmo Salo helped prepare the manuscript. Jari Räsänen supervised and contributed to the manuscript. All authors read and approved the final study protocol.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

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